

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (the Act) and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted or are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 84C(1E) of the Act provides that the regulations may prescribe the ‘value for safety net purposes’ of a supply of a pharmaceutical benefit. Subsection 84C(1F) of the Act provides that the value must take into account the amount charged for the supply, but may make adjustments for safety net purposes such as excluding certain components of the amount charged or setting a maximum limit on the value.

The *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) prescribe, among other things, for the calculation of the ‘value for safety net purposes’ to determine whether a person is entitled to be issued with a safety net concession card or pharmaceutical benefit entitlement card under Division 1A of Part VII of the Act. Section 87 of the Act provides that the holder of a safety net concession card or a pharmaceutical benefit entitlement card is entitled to be supplied pharmaceutical benefits at a lower price or free of charge during the relevant entitlement period once the relevant thresholds are met.

Regulation 17A of the Principal Regulations prescribes the ‘value for safety net purposes’ of the supply of a pharmaceutical benefit for the purposes of the Act. Regulation 17A provides that the value of any ‘additional patient charge (or part thereof)’ that an approved pharmacist charges a patient in respect of the dispense of a pharmaceutical benefit is not to be counted towards determining the ‘value for safety net purposes’.

Regulation 5(1) of the Principal Regulations defines ‘additional patient charge’ by reference to clauses 5.2.2(c) or 5.2.3(c) of the Sixth Community Pharmacy Agreement. The Sixth Community Pharmacy Agreement is an agreement between the Commonwealth, through the Minister for Health and the Pharmacy Guild of Australia.

On 11 June 2020, the Commonwealth, through the Minister for Health, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia Limited signed the Seventh Community Pharmacy Agreement, which replaces the Sixth Community Pharmacy Agreement with effect from 1 July 2020. The Seventh Community Pharmacy Agreement includes clauses that set the additional patient charge that an approved pharmacist may charge a patient in respect of the supply of pharmaceutical benefits. A copy of the Seventh Community Pharmacy Agreement can be found at the Department of Health's website at: <https://www1.health.gov.au/internet/main/publishing.nsf/Content/New-7th-Community-Pharmacy-Agreement>

Consultation

The Pharmacy Guild of Australia was consulted on the change to the further additional patient charge prior to the signing of the Seventh Community Pharmacy Agreement. No specific consultation was undertaken in relation to the Regulations as they provide for a technical amendment related to the implementation of the Seventh Community Pharmacy Agreement that is similar to the existing arrangements.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations is exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after the Regulations are registered.

Details of the proposed *National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020*

Section 1 - Name

This section provides that the title of the instrument is the *National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020*.

Section 2 - Commencement

This section provides for the instrument to commence on the day after the instrument is registered.

Section 3 - Authority

This section provides that the instrument is made under the *National Health Act 1953*.

Section 4 - Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 - Amendments

National Health (Pharmaceutical Benefits) Regulations 2017

Item [1] - subsection 5(1)

Subsection 5(1) of the Principal Regulations is amended to provide that ‘additional patient charge’ means the further additional patient charge referred to in clause 4.2.1(c) or 4.2.2(c) of the Seventh Community Pharmacy Agreement, as in force on 1 July 2020.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020

The *National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020* (the Amendment Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Regulations

The Amendment Regulations are made under section 140 of the *National Health Act 1953* (the Act). Section 140 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act. Subsection 84C(1E) of the Act further provides that regulations may prescribe the ‘value for safety net purposes’ of the supply of a pharmaceutical benefit.

The Amendment Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). The Amendment Regulations establish the amounts for the purposes of determining the ‘additional patient charge’ for the purpose of calculating the value for safety net purposes in order to determine if a person is entitled to be issued with a safety net concession card or a pharmaceutical benefit entitlement card under the Act. The holder of a safety net concession card or a pharmaceutical benefit entitlement card is entitled to be supplied pharmaceutical benefits at a lower price or free of charge during an entitlement period once the relevant thresholds are met.

The amount of the additional patient charge has been agreed between the Commonwealth, through the Minister for Health and the Pharmacy Guild of Australia in the Seventh Community Pharmacy Agreement to commence from 1 July 2020.

The Amendment Regulations are required to ensure that approved pharmacists are able to continue to record against patients’ safety net, the correct value for the purposes of determining the price of a pharmaceutical benefit for safety net purposes, where approved pharmacists charge patients an additional patient charge. Regulation 17A of the Principal Regulations provides that the value of any ‘additional patient charge (or part thereof)’ that an approved pharmacist charges a patient in respect of the dispense of a pharmaceutical benefit is not to be counted towards determining the value for safety net purposes. The Amendment Regulations update the amount of the additional patient charge that must be deducted from the value calculated for safety net purposes to reflect the amount of the additional patient charge agreed between the Commonwealth, through the Minister for Health, and the Pharmacy Guild of Australia in the Seventh Community Pharmacy Agreement.

Human rights implications

The Amendment Regulations engage Article 2 and Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS and the safety net scheme under the Act are benefit schemes which assist with advancement of this human right by providing subsidised access by patients to medicines.

Conclusion

The Amendment Regulations are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms. Human rights continue to be protected by ensuring the access to affordable medicines to Australians.

The Hon Greg Hunt MP

Minister for Health